

Tulane University Human Research Protection Office
Biomedical IRB Consent Form for Participation in a Research Study

PDL-1 inhibition with Avelumab and concurrent second-generation ADT in African Americans with castrate-resistant metastatic prostate cancer.

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Study Title: PDL-1 inhibition with Avelumab and concurrent second-generation ADT in African Americans with castrate-resistant metastatic prostate cancer.

ClinicalTrials.gov Identifier: NCT03770455

Performance Sites: Tulane Medical Center, 1415 Tulane Avenue, New Orleans, LA 70112
Tulane Cancer Center, 150 S. Liberty Street, New Orleans, LA 70112

Sponsor: EMD Serono, Inc.; Tulane University Medical Center

The following informed consent is required by Tulane University for any research study conducted by investigators at Tulane University. This study has been reviewed by the Tulane University Institutional Review Board for Human Subjects.

Introduction

You are invited to participate in a research study to evaluate the response to Avelumab in African American men with metastatic castrate resistant prostate cancer (mCRPC). You are being asked to take part in this research study because you have metastatic prostate cancer (prostate cancer that has spread to other parts of your body).

Research studies are voluntary and include only people who choose to take part. Please read this consent form carefully and take your time making your decision. As your study doctor or study staff discusses this consent form with you, please ask him/her to explain any words or information that you do not clearly understand. We encourage you to talk with your family and friends before you decide to take part in this research study.

Please tell the study doctor or study staff if you are taking part in another research study.

If you agree to participate in this research study, no research activity is to be conducted until you have had an opportunity to review this consent form, ask any questions you may have, and sign this document.

This consent form will give you the information you will need to understand why this study is being done and why you are being invited to participate. It will also describe what you will need to do to participate and any known risks, inconveniences or discomforts that you may have while participating. We encourage you to ask questions now and at any time. If you decide to participate, you will be asked to sign this form and it will be a record of your agreement to participate. You will be given a copy of this form.

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Approximately a total of 13 African American men will take part in this study.

Disclosure of Potential Conflict of Interest

The investigators in this study are also healthcare providers. They are interested in the knowledge to be gained from this study and are interested in your well-being. Tulane Health Sciences Center receives funding from EMD Serono to help cover administrative costs of conducting this study. Additionally, investigators may obtain salary or other financial support from the sponsor in exchange for conducting this study. You are under no obligation to participate in any research study offered to you.

EMD Serono Inc. (“Sponsor”) is providing the drug and financial support for this research trial. EMD Serono is the company that is developing the investigational drug avelumab.

Why is this study being done?

The purpose of this study is to evaluate the response to Avelumab in African American men with metastatic castrate resistant prostate cancer (mCRPC).

Avelumab is an investigational drug, which belongs to a family of molecules called anti-PD-L1 antibodies. PD-L1 is a cell surface protein, found in different human tumor types, which is considered to be able to inhibit an anti-tumor response of the immune system. Avelumab interferes with the activity of PD-L1 and is thought to potentially have an effect on the immune system (in particular white blood cells) in order to induce an anti-tumor attack.

It is possible that African American men are more responsive to the inhibition of the PD-1 signaling pathway. We are trying to find out what effects, good and/or bad, Avelumab has on you, and whether Avelumab is effective in treating mCRPC.

Avelumab is an investigational drug, in this disease. An investigational drug is one that is not approved for sale. Avelumab has been used in different diseases, such as Merkel cell carcinoma and urothelial carcinoma (bladder cancer).

What are the study procedures? What will I be asked to do?

Subject Responsibilities: If you are eligible and decide to take part in the study, you will need to do the following things:

- Report to the study clinic for all scheduled visits and other visits as requested by the study staff
- Report any reactions or unwanted side effects (adverse events) to your study doctor
- Report taking any additional medications to your study doctor. This includes vitamins, dietary supplements, herbal or alternative remedies, medications that are prescribed by a doctor, and over-the-counter medications. If you feel that you need to take a new medication or herbal remedy, you must call the study doctor and get approval before taking the medication.
- Blood and laboratory tests
- Radiology assessments via CT scan and bone scan

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The study staff will record the above information in your study records and follow any adverse event (side effect) that may occur. It is important that you immediately report any new symptoms or worsening of symptoms that you have to the study staff.

You will continue to take the hormone therapy (Zytiga (abiraterone acetate), Xtandi (enzalutamide), Erleada (apalutamide), or ODM-201 (darolutimide)) and androgen deprivation therapy (ADT), that you have been prescribed. Receiving any other prostate cancer therapy or other investigational drugs is not allowed while you are participating in the study. The study staff will discuss these restrictions with you in more detail.

Participation in this research study is completely voluntary. If you choose not to sign this consent form you will continue to receive care, but not as part of this study.

Screening Phase:

Before you begin the study: If you agree to be in this study, you will be asked to sign and date this consent form. You will need to have the following exams, tests or procedures to find out if you can be in the study. This visit will last about 2 hours. These may be a part of regular care for someone who has mCRPC. If you have had some of them recently, they may not need to be repeated. This will be up to your study doctor.

- You will be asked questions about yourself and your health problems, including past surgeries and past treatments for your prostate cancer.
- You will be asked about medications that you are currently taking, including over-the-counter medications, herbal remedies, vitamins, and supplements.
- You will have a physical examination, which will include measuring your temperature, blood pressure, height, weight, heart rate, breathing rate, and health status.
- You will be asked about any disease-related symptoms you are experiencing.
- You will have an electrocardiogram (ECG) performed to measure the electrical activity of your heart.
- You will have a computed tomography (CT) scan or a magnetic resonance imaging (MRI) of your chest, abdomen, and pelvis, and if needed, other areas to evaluate your disease. A CT scan uses special x-ray equipment to take pictures of the body. The MRI scan uses magnetic and radio waves, meaning that there is no exposure to ionizing radiation. For the CT and MRI scan, you will be asked to lie down and keep still in the scanner for approximately 20 minutes. An x-ray of your chest may also be performed if necessary. You will only get an MRI if you are unable to undergo a CT scan due to allergy or other reason.
- You will have a bone scan to identify changes involving the bone such as tumor or fracture. A bone scan uses bone-seeking radioactive material that is injected into a vein so it travels through the bloodstream. The radiation is detected by a camera that scans your body and takes pictures of how much the radioactive material collects in the bones.
- A sample of your blood (about 3 to 4 tablespoons) will be collected. This blood will be collected for routine safety blood tests, Prostate Specific Antigen (PSA), testosterone levels, thyroid function levels,

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and for other specialized research laboratory tests. These specialized research laboratory tests are used for biomarker and DNA analysis.

- A sample of your urine will be collected for routine safety tests
- If available, tumor tissue will be collected from either your previous biopsy or surgical specimen, or from a newly obtained biopsy for DNA research. If not available, you are still able to participate in the study.

If you are eligible to take part in the study, you will be asked to return to the clinic to receive your study drug. If you are not eligible, the study staff will discuss other treatment options with you.

Treatment Phase:

The study can be divided into periods of time called “cycles”. A cycle in this study will last 14 days. At the start of each cycle, you will be asked to visit the clinic to receive study drug and have regular pre-scheduled check-ups and lab assessments.

How long will I be on the study drug? Study participation will vary from person to person. Generally you will stay on the study drug until any of the following occurs:

- Your disease gets worse
- You experience a serious side effect
- You develop another illness that prevents you from receiving treatment
- You do not follow the instructions of the study doctor
- You receive 52 study drug infusions (2 years)
- The study doctor thinks that study treatment is no longer in your best interest

During the study

- Take the investigational study drug:
 - Avelumab will be administered by an infusion into one of your veins. The infusion lasts about 30 minutes. Avelumab will be given as a 10mg/kg dose on Day 1 of every 2 week treatment cycle. The time between doses of avelumab will be approximately every 14 days (2 weeks). The time between doses may increase if you experience bad side effects.
- Take the other non-investigational study drug:
 - Continue to take the hormone therapy (Zytiga (abiraterone acetate), Xtandi (enzalutamide), Erleada (apalutamide), or ODM-201 (darolutimide)) and androgen deprivation therapy (ADT), that you have been prescribed.

Study visits will last 1-1.5 hours. The following assessments will occur at all study visits:

- You will be asked about the medications you are currently taking, including all prescribed medications, over-the-counter medications, herbal remedies, vitamins, and supplements.

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- You will be asked about any new or continuing side effects or illnesses you have had since your last visit.
- You will have a physical examination, which will include having your weight, temperature, blood pressure, heart rate, and breathing rate measured.
- A sample of your blood (about 3 to 4 tablespoons) will be collected. This blood will be collected for routine safety blood tests, and tumor markers such as Prostate Specific Antigen (PSA).

On Study Day 1 of Cycle 2 and every 4 cycles or 8 weeks, treatment discontinuation, and the safety follow-up visit these additional assessments will occur.

- A sample of your blood (about 2 tablespoons) will be collected for thyroid function testing
- A sample of your urine will be collected for routine safety tests
- A sample of your blood (about 2 tablespoons) will be collected to measure your testosterone levels

Every 12 weeks from the start of study:

- Imaging assessments (CT/MRI and bone scans). Imaging assessments will take about 1-1.5 hours.

What if my disease worsens?

If the assessment of your cancer by CT/MRI, or bone scan shows that your cancer may have worsened, you may be asked to have another radiographic assessment performed a minimum of 4 weeks later to confirm the worsening. The study doctor will discuss your options during the period between scans, which may include the following:

- Continue to receive treatment with the study drug or;
- Hold the study drug until the time that the worsening is confirmed or;
- Discontinue from the study drug
- End treatment in the study, and start alternative treatments such as approved chemotherapy drugs, alternative hormonal therapy, other investigational therapies etc. Your study doctor will discuss what drugs are approved and available for treatment in your region.
- Terminate all treatment and move on to palliative or comfort care

If you elect to wait until the confirmation scan, you will not be eligible to receive any other medications except your study medication until the worsening of your disease is confirmed and study treatment is stopped. If the follow up radiographic assessment (after the assessment that first showed worsening of your cancer) shows that the size of your tumor has not increased further and your doctor thinks you are doing well you may be eligible to continue on the study drug.

When you are finished taking study drug:

End of Study Visit: An End of Study visit will be scheduled at the time of discontinuation. At this visit, the following procedures, in addition to the assessments done at all visits, will be performed:

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- A sample of your blood (about 3 to 4 tablespoons) will be collected. This blood will be tested for routine safety blood tests, PSA level, thyroid function testing, circulating tumor cell count and testosterone.
- A sample of your urine will be collected or routine safety tests
- Imaging assessments (CT/MRI and bone scans). If a previous scan was done within 4 weeks prior to your end of study date, another scan isn't needed.

Safety Follow-up Visit: When you stop taking study drug, you will be asked to come in for a safety follow-up visit about 30 days after your last study drug treatment or before you start new treatment for your cancer, whichever comes first. You will then enter the post-treatment follow-up period. The study doctor or staff will discuss with you when and on which days to report to the clinic for the follow-up visits. At this visit, the following procedures, in addition to the assessments done at all visits, will be performed:

- A sample of your blood (about 3 to 4 tablespoons) will be collected. This blood will be tested for routine safety blood tests, thyroid function testing, circulating tumor cell count and testosterone.
- A sample of your urine will be collected or routine safety tests

Routine follow up visits: Routine follow up visits will be scheduled every 12 weeks after your last dose of study drug to continue to monitor your health, for up to one year. Sometimes drugs like avelumab continue to work even after treatment stops. The study is designed to measure this potential effect. Consequently, it is important to continue to be followed in the study even after you stop treatment. At this visit, the following procedures will be performed:

- You will be asked about your current anti-cancer therapy.
- You will be asked about any new or continuing side effects or illnesses you have had since your last visit.
- If you discontinued treatment and entered follow up without confirmed disease progression, your study team will ask you to for the following; until your cancer gets worse or you start a new treatment for your cancer:
 - Collect a sample of your blood (about 3 to 4 tablespoons) will be collected. This blood will be collected for Prostate Specific Antigen (PSA).
 - Imaging assessments (CT/MRI and bone scans). If a previous scan was done or is scheduled within 4 weeks of the visit, another scan isn't needed.

If at any time during post-study drug treatment your cancer gets worse, or you start a new cancer treatment, you will move into the survival follow up phase.

Survival follow up: We would like to contact you every 6 months to discuss your current anti-cancer therapy and verify your survival status. This visit can be conducted during a standard of care office visit or via telephone.

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Additional blood: If your blood collected at baseline for DNA research is not evaluable, an additional sample of your blood (about 1 teaspoon) may be collected in order to complete the DNA research. This sample can be collected anytime during the study. Your study doctor or nurse will explain if this applies to you.

How long will I be in the study?

If you decide to participate, you will be on this study for the rest of your life, or until the study closes. You will be asked to remain active on study drug for two years or until your cancer worsens (according to the CT/MRI, or bone scan results), you are unable to tolerate the study drug, your doctors determines that you should begin another cancer treatment, or you decide to withdraw consent.

After your follow-up safety visit, you will visit the clinic about once every 3 months for up to 12 months after starting the study. If you discontinued study drug for reasons other than disease progression, clinic study staff will collect information related to the progression of your disease (for example standard of care scans, standard of care labs, new therapies) to follow you until your disease gets worse. After all of your study and follow up visits are completed, we will continue to contact you by phone every 6 months to find out the status of your health.

You can choose to stop participating at any time without penalty or loss of any benefits to which you are entitled. However, if you decide to stop participating in the study, we encourage you to talk to your doctor first.

Information about DNA testing:

Some of the blood samples collected will be used for genetic studies. Your genes are made of DNA, which is short for deoxyribonucleic acid. A gene, or DNA, contains information that determines in part the traits, such as eye color, height, or disease risk, that are passed on from parent to child. For this study, we will be examining how differences in your genes may affect how you respond to the study drug.

It is possible that this genetic study will identify information about you that was previously unknown, such as disease status or risk. We will provide this information to you. In that case, we will attempt to notify you using the contact information you have provided, so that you can speak with a doctor. Study staff will not provide this information in a voice mail, email, or otherwise prior to contacting you. Please notify us of any change in your contact information.

After providing the information to you, your Doctor may arrange for you to meet with him and/or a genetic counselor or refer you to another appropriate health care provider to review the incidental findings information with you or your physician.

DNA can change or be damaged over time. These abnormal changes in DNA are called genetic mutations. Some DNA changes are harmless, but others can cause disease. Cancer cells are “born” when abnormal changes in DNA tell cells to grow faster and behave differently than they should. As these cancer cells multiply to form a tumor, they continue to change – becoming more and more different from each other. As a cancer grows, new and different types of cancer cells are created within that same cancer. The mixture of cells that builds up over time becomes more and more complex. So even though every cell of a cancer is

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related to the same original "parent" cell, all the cells that make up a cancer are not the same. Over the course of the study we will collect blood samples and a sample of tissue (if available or feasible) to look at the DNA of your tumor. Some of these tests will only be completed if you respond to the study medication.

_____ (Subject Initials) **I allow my blood and tissue to be tested for information regarding my TUMOR's DNA**

_____ (Subject Initials) **I will not allow my blood and tissue to be tested for information regarding my TUMOR's DNA**

What alternatives are there?

If you should decide not to participate in, or if you withdraw from this study, the study doctor can recommend other treatments.

Alternative treatments for your cancer include:

- A marketed drug or treatment with a different drug
- Other clinical trials
- Alternative hormonal therapy
- Chemotherapy
- If you decide you don't want any more active treatment, one of your options is "comfort care". Comfort care includes pain medication and other support. It aims to maintain your comfort and dignity rather than cure disease. Usually this care can be provided at home.

If you have questions about alternate treatments and their potential benefits and risks, ask the study doctor for additional information. You do not need to participate in this study to be treated for your advanced cancer.

What are the risks, discomforts or inconveniences of the study?

In a clinical study like this one, every risk or side effect cannot be predicted. Each person's reaction to an investigational drug, device or procedure may be different. You may have a side effect or be at risk for symptoms, illnesses and or complications that could not be predicted by your study doctor or the study team of this clinical study.

It is possible that the symptoms of your condition will not improve during the study or may even worsen.

For your safety, you must inform your study doctor about all **medicines, vitamins, and herbal supplements you are taking. In addition, you must inform them about any adverse effects.**

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Three types of risks are associated with avelumab: general signs and symptoms, reactions that occur during or following the infusion (so called infusion-related reactions), and immune side effects. The following general side effects have been observed in $\geq 10\%$ of patients among 1738 patients treated with avelumab according to the results from two oncology clinical studies in patients with various solid tumors:

Observed in 10% or more of patients	
<ul style="list-style-type: none"> • Fatigue (tiredness) • Nausea (feeling sick to the stomach) • Diarrhea Frequent loose, watery stools • Constipation (difficulty passing stools) • Decreased appetite • Infusion related reaction • Weight decreased • Vomiting • Anemia (low number of red blood cells) • Abdominal pain • Cough • Pyrexia (fever) 	<ul style="list-style-type: none"> • Dyspnea (shortness of breath) • Pruritus (itching) • Edema peripheral (build-up of fluid in the body causing swelling) • Musculoskeletal pain (including back pain, neck pain) • Arthralgia (joint pain) • Dizziness • Headache • Hypertension (increase in blood pressure) • Urinary tract infection

The following side effects (regardless of relationship to study drug) have been observed in less than 5% of the patients treated with the study drug:

- rash
- non-cardiac chest pain

Allergic reactions or reactions in the context with the infusions might occur during or after the infusion. Although avelumab is a fully human protein the risk cannot be completely excluded. Symptoms may include chills or shaking, fever, flushing, back pain, belly pain, shortness of breath or wheezing, decrease in blood pressure, and hives. Infusion-related reactions have already been observed under treatment with avelumab. In general, these reactions are mild to moderate and generally resolve with a slowdown or discontinuation of the infusion and with appropriate drugs, but in very rare cases severe to life-threatening (less than 1%) and even fatal reactions (not observed with avelumab) might occur, which require advanced cardiac life support. For the prevention of infusion-related adverse effects and possible allergic reactions you will receive a premedication of an antihistamine drug (so-called H1 blocker) and acetaminophen 30 to 60 minutes before every infusion.

In addition, side effects resulting from an increased activity of the immune system have also been observed. The side effects listed below may be temporary, long term, permanent or result in death. However, most of these side effects are reversible. That means they will stop once the drug is discontinued. The reactions that are more severe require treatment with drugs that decrease the immune system function, also called

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immunosuppressant drugs (like corticosteroids or more potent drugs). No immune side effects were observed in 10% or more of patients.

The following immune-mediated side effects have been observed in patients receiving the study drug and might occur, such as:

Immune side effects observed in 5% to less than 10% of patients

- **Abnormal function of the thyroid gland (could include low or high function or inflammation of the thyroid gland):** may include rapid heartbeat; increased sweating; extreme tiredness; weight gain or weight loss; hair loss; changes in mood or behavior such as irritability or forgetfulness; feeling cold; constipation; voice gets deeper.
- **Inflammation of the skin (rash):** may include skin rash, itchy skin, skin redness, skin blisters, or peeling.

Immune side effects observed in 1% to less than 5% of patients

- **Inflammation of the large intestine (colitis):** may include diarrhea (loose stools) or more frequent bowel movements than usual; blood in stools or dark, tarry, sticky stools; severe stomach area (abdomen) pain or tenderness.
- **Inflammation of the lungs (pneumonitis):** may include new or worsening cough, shortness of breath, chest pain.

Immune side observed in less than 1% of patients:

- **Inflammation of the liver (hepatitis):** may include yellowing of skin or of the whites of eyes; severe nausea or vomiting; pain on the right side of stomach area (abdomen); drowsiness; dark urine (tea colored); bleeding or bruising more easily than normal; feeling less hungry than usual.
- **Inflammation of the kidneys (nephritis):** may include urinating less than usual; blood in urine; swelling in ankles; loss of appetite.
- **Low function of the adrenal glands (glands on top of the kidneys),** which may be due to the reduced function of the pituitary gland (a gland in the head): may include very low blood pressure; extreme tiredness.
- **Increase in blood sugar (diabetes):** may include urinating more often than usual; feeling more hungry or thirsty than usual, nausea or vomiting, stomach area (abdomen) pain.
- **Inflammation of the eyes (uveitis):** may include changes in eyesight.
- **Inflammation of the muscles (myositis):** may include severe or persistent muscle or joint pain; severe muscle weakness.
- **Inflammation of the heart (myocarditis):** may include chest pain or tightness; tiredness; changes in heartbeat, such as beating fast, or seeming to skip a beat, or pounding sensation; swelling of feet and legs; trouble breathing.
- **Inflammation of the nerves (Guillain-Barre syndrome):** may include "pins and needles" sensations in arms and legs; weakness in legs that spreads to the upper body and may lead to temporary paralysis.

Single cases of immune-mediated pneumonitis, immune mediated hepatitis and immune-mediated myocarditis with fatal outcome have been observed with avelumab.

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If any of these side effects occur, you must inform your study doctor immediately.

Please share this information with your partner:

It is not known whether taking the investigational drug will affect sperm or semen, or can result in genetic mutations or other deformities in an unborn child. Therefore, you should not take part in this clinical study if you intend to father a child during the clinical study. Also, it is unknown whether taking the investigational drug can affect your ability to father children in the future.

If your partner is capable of becoming pregnant, you must agree to avoid sexual intercourse or use a highly effective form of contraception (this means contraception methods with a failure rate of less than 1% per year) during the study as described before. Examples of highly effective contraception methods are:

- hormonal contraception (containing estrogen and progesterone or progesterone alone) associated with inhibition of ovulation
- intrauterine device (IUD)
- intrauterine hormone-releasing system (IUS)
- bilateral tubal occlusion
- vasectomized partner (after medical assessment of the surgical success)

Individual methods of contraception should be discussed and determined with your study doctor. Your abstinence or use of contraception should be continued for at least 60 days after you received the last infusion of study drug.

If your partner does become pregnant during the course of the clinical study or within 60 days of receiving the last infusion of study drug, you must tell your study doctor **immediately**.

Your study doctor will be required to collect information about the outcome of your partner's pregnancy, and provide this information to the study team.

Other side effects linked to medical procedures during the clinical study

Blood samples

You will need to have samples of blood taken during the clinical study for laboratory testing. You may experience temporary discomfort from this. The needle sticks may cause local pain, bruising, swelling, lightheadedness, dizziness and rarely, fainting and/or a possible infection from the needle stick.

Electrocardiogram (ECG)

This test is not invasive and uses small sticky pads that are placed on your chest, arms and legs to measure the electrical activity of your heart. There may be mild discomfort from the sticky pads and a possibility of the skin being irritated by the adhesive on the sticky pads. Some hair may need to be shaved prior to the placement of the sticky pads.

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Ionizing Radiation exposure

CT and bone scans in the clinical study will mean you are exposed to more radiation than normal, which could lead in the worst case to any radiation associated diseases in the future. The contrast substance injected during the CT scan may cause pain, burning feeling, sweating and rarely a serious allergic reaction that can be serious - if you know you're allergic to iodine; you must inform your doctor immediately. The contrast agent used in the CT scan may cause kidney damage, especially if you are diabetic, dehydrated and if you are older. In addition, the thyroid function may be affected. Please inform your doctor if you meet these particular risk factors.

If a CT scan is not recommended by your study doctor, instead a MRI may be performed which does not use radiation. For your MRIs, you will receive a contrast agent called gadolinium administered intravenously prior to each MRI. It will allow for a better image to be seen during the MRI. This contrast agent may occasionally cause nausea and vomiting. Very rarely, it may cause slight warmth or pain at the injection site. Allergic reactions may also occur very rarely, and, in extremely rare instances, these can be potentially serious. If you suffer from a renal disease, the contrast dye that is injected while the MRI scan is taken may be poorly tolerated and therefore, it is important to advise your doctor if you are suffering from a renal (kidney) disease. Also if you have had any type of device placed inside your body for medical reasons (e.g. pacemaker, cerebral aneurysm clips or a heart valve replaced), you should inform your doctor as you may not be able to have an MRI.

Breach of Confidentiality:

In addition, there is a low risk of breach of confidentiality associated with the study, however personal identifiers will be replaced with a code and access to the data will be only by those who are authorized to access. Methods to prevent a breach of confidentiality are listed later in the form under "How will my personal information be protected?".

What If Relevant New Information Becomes Available?

Sometimes during the course of a research trial, new information becomes available about the investigational drug. If this happens, your trial doctor will tell you about it and discuss whether you want to or should continue in the trial. If you decide not to continue, your trial doctor will discuss potential options for your care. If you decide to continue in the trial, you will be asked to sign an updated consent form.

What are the benefits of the study?

You may not personally benefit from taking part in the trial; there is no guarantee that avelumab will prevent the further development of your cancer. However, the information gained may help in the treatment of other subjects with solid tumor cancer or other types of cancer in the future and/or to advance knowledge about the use of this investigational drug in subjects with solid tumor cancer or other types of cancer.

Will I receive payment for participation?

You will not be paid to be in this study.

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Are there costs to participate?

Some of the tests or treatments used in this study may be part of standard care used to maintain your health even if you did not take part in this study. You or your insurance company may be responsible for the cost of this standard care. All trial medication and trial-related tests will be provided at no cost to you.

The following items will be paid for by the study:

- Study drug and infusion
- ECG
- Urinalysis
- Blood tests - Free Thyroxine (FT4) and thyroid stimulating hormone (TSH)
- Tumor tissue collection

How will my personal information be protected?

If you decide to be in this study, the study doctor and research team will use health data about you to conduct this study, as described in this consent document. This may include your name, address, phone number, medical history, photographs, date of birth, and information from your study visits. This health data may come from your family doctor or other health care workers.

It is the intent of the Sponsor and study staff that the health data that is shared as a part of the study will not identify you. Your name will be replaced with a study number, your initials, date of birth, and study visit dates. The study number will be a unique code assigned to you as you are added to the study. There may be a remote chance that information that identifies you may accidentally be shared. If that were to happen, both the study team and Sponsor would work together to remove the information that identifies you from their records. You will not be identified by name in any published reports about this study or in any other scientific publication or presentation. If you think that you were harmed from being in the study, the study team may also share health data about you with the hospital's insurer to resolve your claim.

The following procedures will be used to protect the confidentiality of your data (and/or specimens). The researchers will keep all study records (including any codes to your data (and/or specimens)) locked in a secure location. A master key that links names and codes will be maintained in a separate and secure location. All electronic files (*e.g.*, database, spreadsheet, etc.) containing identifiable information will be password protected. Any computer hosting such files will also have password protection to prevent access by unauthorized users. Only the members of the research staff will have access to the passwords. Data (and/or specimens) that will be shared with others will be coded as described above to help protect your identity. At the conclusion of this study, the researchers may publish their findings. Information will be presented in summary format and you will not be identified in any publications or presentations. Any master key, audio recording, and other data described in this paragraph will be maintained in accordance with the security provisions of this paragraph until destroyed by the researchers.

The study team, which may include affiliates of the team, may use the health data sent to them:

- to see if the study drug works and is safe;
- to compare the study drug to other drugs;
- to develop new tests

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- for other activities (such as development and regulatory) related to the study drug.

For these uses, the study team may share this health data with others involved in these activities, as long as they agree to only use the health data as described here. The study team and those working for or with the team, which may include affiliates of the team, may transfer health data about you from your country to other countries where the privacy laws are not as strict. Once the research team shares health data about you with others, it may no longer be protected by privacy laws.

There is a risk that if people other than the study staff, or those working for or with the Sponsor, may get your health data and genetic information they could misuse it for purposes other than those outlined in this consent. The study team has strict privacy and confidentiality protection procedures in place to prevent this from occurring so the chance of this happening to you is extremely small.

You may take away your permission to use and share health data about you at any time by writing to the study doctor. If you do this, you will not be able to stay in this study. Health data about you that has already been gathered may still be used and given to others as described in this document.

To ensure the scientific integrity of the study, you may not be able to review some of your records related to the study until after the study has been completed. When the study is over, you may write to the study doctor to ask to see health data about you that was collected during the study and to correct any errors. Results obtained from planned genetic research will not be provided back to you or the study doctor.

You should also know that the Tulane University Human Research Protection Office and the Biomedical Institutional Review Board (IRB) may inspect study records as part of its auditing program, but these reviews will only focus on the researchers and not on your responses or involvement. The IRB is a group of people who review research studies to protect the rights and welfare of research participants.

To the extent allowed by law, every effort will be made to keep your personal information confidential. However, information from this study will be submitted to the study team and to the U.S. Food and Drug Administration. It may be submitted to governmental agencies in other countries where the study drug may be considered for approval. Medical records, which identify you and the consent form signed by you, will be looked at by the study team or the study team's representatives and may be looked at by the FDA and other regulatory agencies.

A federal law called the Genetic Information Nondiscrimination Act ("GINA") generally makes it illegal for health insurance companies, group health plans and most employers to discriminate against you based on your genetic information. This law generally will protect you in the following ways:

- Health insurance companies and group health plans may not request your genetic information that we get from this research.
- Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.

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- Employers with 15 or more employees may not use your genetic information that we get from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.
- Be aware that this federal law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

What happens if I am injured or sick because I took part in the study?

If you need immediate assistance, go to your nearest emergency room for treatment or dial 911 and inform emergency personnel that you are in this study.

In the event you become sick or injured during the course of the research study, immediately notify the principal investigator or a member of the research team. The Tulane University Health Sciences Center and the investigators in this protocol will provide necessary medical treatment for any injury or illness which may arise from your participation in this research

We reserve the right to bill you, your insurance company or other third parties, if appropriate, for the medical care you receive to treat an injury or illness that arises from or during you participation in the study. You will be responsible for payment of any deductibles, coinsurances and co-payments required by your insurer, and if your insurer or other third party refuses to pay for the medical care you get for the injury or illness, you will be responsible for paying costs associated with treatment.

The Tulane University Health Sciences Center and the sponsor do not offer any form of compensation (such as payment for lost wages or for emotional suffering) if you suffer injury or illness arising from participation in this research. You are not giving up any of your legal rights by signing this form.

If you have any questions about your rights as a research subject, please call the Tulane University Human Research Protection Office at (504) 988-2665 or email irbmain@tulane.edu.

Can I stop being in the study and what are my rights?

You do not have to be in this study if you do not want to. If you agree to be in the study, but later change your mind, you may drop out at any time. There are no penalties or consequences of any kind if you decide that you do not want to participate.

If you withdraw from the study, no new data about you will be collected for study purposes unless the data concern an adverse event (a bad effect) related to the study. If such an adverse event occurs, we may need to review your entire medical record. All data that have already been collected for study purposes, and any new information about an adverse event related to the study, will be collected.

Your doctor may decide to take you off this study if your condition gets worse, if you have serious side effects, if your study doctor determines that it is no longer in your best interest to continue, you do not follow the procedures of the study, or you start another prostate cancer therapy. The study team and regulatory agencies may stop this study at any time without your consent. If this occurs, you will be notified, and, your study doctor will discuss other options for treatment.

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You may withdraw your consent at any time. The information collected prior to your withdrawal of consent will still be part of the study data. However, no new information will be collected.

We will tell you about new information that may affect your health, welfare, or willingness to stay in this study.

Who do I contact if I have questions about the study?

Take as much time as you like before you make a decision to participate in this study. We will be happy to answer any question you have about this study. If you have further questions about this study, want to voice concerns or complaints about the research or if you have a research-related problem, you may contact the principal investigator, Jodi L. Layton, MD at or 504-988-6300 (clinic) or the clinical coordinators Patrick Cotogno at 504-988-6542 or Charlotte Manogue at 504-988-3908.

If you would like to discuss your rights as a research participant, discuss problems, concerns, and questions; obtain information; or offer input with an informed individual who is unaffiliated with the specific research, you may contact the Tulane University Human Research Protection Office at 504-988-2665 or email at irbmain@tulane.edu.

A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This web site will not include information that can identify you. At most, the web site will include a summary of the results. You can search this web site at any time.

You will receive a wallet ID card identifying you as a subject on this study. This card also has contact information in case of emergency or evacuation.

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I am unable to read but this consent document has been read and explained to me by _____ (name of reader). I volunteer to participate in this research.

Subject Date

Impartial Witness Date

Person Obtaining Consent Date